DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director

Report of the Director's Discretionary Fund
Third Quarter of FY 2018

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Report of the Director's Discretionary Fund

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Introduction

The report accompanying the fiscal year (FY) 2018 Labor, Health and Human Services, Education, and Related Agencies House bill stated the following:

> "The Committee continues the bill language for specific funds authorized by the Gabriella Miller Kids First Research Act within the CF to support the third year of the 10-year Pediatric Research Initiative. The Committee urges the Director to use a portion of the $10,000,000 made available to the Director's Discretionary Fund (DDF) to support additional pediatric research. The Committee requests, within 30 days after the end of each fiscal year quarter, a quarterly report on DDF obligations for each activity supported. The report should include a description of the program, which ICs are to provide continuation costs, and how this research serves a high priority for pediatric diseases. The quarterly reports shall be posted on-line via the NIH web-site within 30 days after being released to the Committee."

The following report of obligations for the third quarter of FY 2018 has been prepared by the National Institutes of Health (NIH), part of the Department of Health and Human Services, in response to this request. Although the projects listed below were approved for funding during the first and second quarters, the required procurement mechanisms were not in place to enable obligations until the third quarter.

DDF FY 2018 funds supporting pediatric research were obligated in the fourth quarter and will be reported on accordingly.

Background

The DDF is used annually to enable NIH to address high-priority research opportunities and respond to new scientific issues, including through the development of improved management, planning, and analytical tools.

Director's Discretionary Fund
FY 2018
Third Quarter Obligations
(Dollars in Thousands)

IC	Project	Obligations
OD	NIH Workplace Harassment and Climate Communication Strategy	$2
OD	Randomized Controlled Trial on the Impact of Grant-writing Support on R01 Grant-Application Resubmission	$862
NLM	ClinicalTrials.gov	$1,000
FIC	African Postdoctoral Training Initiative	$450
	NIH Total	**$2,314**

Projects Supported by FY 2018 DDF as of the Third Quarter

NIH Workplace Harassment and Climate Communication Strategy

With increasing reports of sexual harassment in academic science, NIH has pledged to identify the steps necessary to end sexual harassment in all NIH research workplaces and scientific meetings. One of the first steps in the identification process is to look within and investigate the prevalence and severity of workplace harassment and sexual harassment within NIH and its impact on people's careers and decisions to stay in science.

The NIH Chief Officer for Scientific Workforce Diversity (COSWD), in collaboration with the NIH Office of the Director's Office of Intramural Research, the Office of Extramural Research, and the Office of Equity, Diversity, and Inclusion, is launching a Trans-NIH Workplace Climate and Harassment Survey, and intends to survey all NIH employees, contractors, fellows/trainees, and volunteers to assess the extent and severity of workplace harassment and sexual harassment at NIH.

The success of the NIH Workplace Harassment and Climate Survey depends on high participation rates, which are contingent upon a successful communications campaign. The goal of the campaign is to broadly advertise and promote the survey and to communicate the purpose and importance of the survey to increase awareness and participation.

Due to NIH's diverse occupational series, locations, and status of employees, contractors, and fellows/trainees, the campaign needs a multi-pronged approach—from campaign design and email promotion to posters, flyers, banners, and lawn signs—to effectively reach a full sample of the population. Without an effective communications campaign, the survey data could result in low response rates or skewed responses from a subset of the NIH workforce, and may not provide valuable insight into prevalence or severity of workplace harassment and sexual harassment.

The funds will be used to develop a visual communications campaign that will increase awareness, and hence, survey response rates. Funds will be obligated to purchase visual design, posters, table tent cards, lawn signs, and the other communications materials (print and web). In addition, funding will be used to hire a part-time contractor to support this effort by communicating and distributing visual materials (e.g., hang posters, distribute handouts, help distribute print surveys to those with no NIH email), if required.

A Randomized Controlled Trial on the Impact of Grant-writing Support on R01 Grant-Application Resubmission

A recent analysis by the NIH's African American/Black Funding Disparity Working Group (DWG), a working group of the Advisory Committee to the Director (ACD), showed that racial disparity in obtaining R01 research project grants has persisted since it was first reported by Dr. Donna Ginther, Professor of Economics and the Director of the Center for Science Technology & Economic Policy at the Institute for Policy & Social Research at the University of Kansas, and her colleagues in 2011. The persistent disparity is a barrier for NIH to foster the most creative, innovative research from all talented investigators regardless of their ethnic or racial backgrounds. A recent letter to *Science* by Dr. John Guers and colleagues also pointed to a similar problem (*Science*, 356, 1018: 2017).

In response to a DWG recommendation, endorsed by the ACD, the NIH Chief Officer for Scientific Workforce Diversity plans to conduct a randomized controlled trial (RCT) to determine whether and how mentoring and coaching on grant-writing will increase resubmission rates and scores of new R01 applications that were discussed but not funded. Because resubmitted applications, on average, have a nearly three-fold increase in success rates than those of an initial application, resubmission presents a critical intervention point to address the funding disparity.

The RCT study will randomly assign a sample of investigators from different racial and ethnic backgrounds who are eligible to resubmit R01 applications into one of two groups: a control group and an experimental group. Investigators in the control group will receive standard feedback from NIH. Investigators in the experimental group will receive comprehensive, structured coaching and mentoring on grant writing over a period of three to four months. Resubmission rates, review outcomes, and eventual success in obtaining funding will be compared between these two groups of investigators. The RCT will monitor the investigators' outcomes for one year after the end of the study.

Funds will be obligated to support a Research and Development contract and NIH staffing to complete Year 1 of the study. Because mentoring and coaching requires small group interaction, the study will be conducted over two waves to reach 90-100 investigators for sufficient statistical power. The study results will help determine the added value of mentoring and coaching on resubmission and funding outcomes. The results will also inform sustainable strategies and solutions in future efforts to eliminate funding disparities and maintain NIH's stewardship in developing the best biomedical and behavioral research.

ClinicalTrials.gov Staff Augmentation for Results Reporting

Since the implementation of the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11) in January 2017, submissions to ClinicalTrials.gov have climbed to more than 320 summary results information data sets per week. That number is expected to increase to 500 per week by the end of FY 2018. National Library of Medicine staff review submissions to ensure that established quality control criteria are met. There is a backlog of more than 2,200 summary results information submissions.

ClinicalTrials.gov aims to continue to advance research and public health by: (1) fulfilling ethical obligations to trial participants and the public; (2) providing rapid dissemination of research findings in a structured, analyzable format; (3) facilitating meta-analyses, systematic reviews, and evidence-based clinical decision making; and (4) bringing basic research from the lab to the medical clinic. Ensuring that the ClinicalTrials.gov database is current, comprehensive, and accurate supports rigor and reproducibility of research, as well as policies and regulations related to clinical trial registration and results reporting. Since one-third of trial results are not published, ClinicalTrials.gov plays a critical role in providing open communication about ongoing clinical research and summary results information in a timely manner.

Funds will be obligated to support increased staffing for reviewing registration and summary results information, outreach/customer service, and project coordination to: (1) process increased submission volumes according to the statutory and regulatory deadlines; (2) improve

submission quality by providing training and support to data submitters; (3) address review process efficiency; and (4) reduce/eliminate the backlog by the end of FY 2018.

African Postdoctoral Training Initiative

NIH, the Bill and Melinda Gates Foundation (BMGF), and other funders have made substantial investments to build research capacity in Africa. These investments advance the search for new interventions, treatments, and cures and improve health, which is a key determinant of development. A core principle is to engage African scientists as partners and independent contributors to the research enterprise. Earlier research in Africa identified the first links between viruses and cancers in humans and provided the first indications that chemotherapy could effectively treat some forms of cancer. More recently, the testing of new drugs and prevention strategies to combat HIV/AIDS was accomplished with engagement of African investigators.

While NIH extramural funding in Africa has rapidly grown, primarily through subcontracts from United States institutions, the NIH Intramural Research Program (IRP) has relatively very few African postdoctoral trainees or scientists. Among the 60 percent of postdoctoral trainees at NIH from abroad, 2 percent of the scientists in the NIH IRP are African.

The BMGF and NIH are planning a pilot program to engage more African scientists in the research enterprise. The Gates – NIH African Postdoctoral Training Initiative (APTI) will bring up to 10 outstanding early- or mid-career African scientists to NIH for two years. Each APTI fellow will train in a global health research area of priority for BMGF, NIH, and their home institutions and countries, while building bridges and connections between NIH and African scientists and institutions and seeding future collaborative partnerships that can build science in Africa. The Alliance for Accelerating Excellence in Science in Africa (AESA) will be a key implementing partner in this initiative. The APTI fellows will be expected to lead important research programs in their home countries and institutions. Travel funds will be made available to APTI fellows for periodic visits home to update activities, maintain scientific and personal links with their home institution, and ultimately prepare for return. After completion of the postdoctoral fellowship, trainees will be provided with 50 percent support for an additional two years to assist their transition into independent research positions in their home countries.

The program will be co-funded by NIH and BMGF. NIH will fund the first year of the program. Out-year funding at NIH and upon re-entry to the home institution, which will be contingent on adequate progress towards completing workplans and project goals, will be provided by BMGF and the host NIH intramural laboratory. Salaries, travel support, and insurance will be managed by the host NIH IRP. An evaluation at the end of year one will help inform a decision about whether to continue the program with enrollment of a second cohort in year three.

Funds will be obligated to support costs associated with postdoctoral fellows' salaries, travel, insurance, training, and administrative expenses incurred during the first year of the program.